Supreme Court, U.S.
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No.

IN THE

SUPREME COURT OF THE UNITED STATES

OCEAN T. ROSE,
LANCE CORPORAL,
UNITED STATES MARINE CORPS, *ET AL.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Armed Forces

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Executive Order 13139, and 10 U.S.C. § 1107, prohibit the administration of investigational new drugs, or drugs unapproved for their applied use, to military servicemembers without their informed consent. In *Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003), the United States District Court for the District of Columbia issued a preliminary injunction barring the Department of Defense from involuntarily administering Anthrax Vaccine Absorbed to servicemembers because the drug was both an investigational new drug and a drug unapproved for its applied use. Petitioners were court-martialed for disobeying orders to receive Anthrax Vaccine Absorbed. The questions presented are:

1. Were the orders given to Petitioners to take Anthrax Vaccine Absorbed lawful when Petitioners had not given informed consent?

2. If the orders given to Petitioners were not barred by Executive Order 13139, and 10 U.S.C. § 1107, do servicemembers have a due process right to refuse unwanted medical treatment, including vaccines that are used as a prophylaxis against chemical and biological warfare?

LIST OF PARTIES

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II. The lower court has decided the important issue of whether the 1.2 million servicemembers now required to receive Anthrax Vaccine Absorbed have the right to refuse unwanted vaccination in a way in conflict with relevant decisions of this Court 13

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OPINIONS BELOW

The principal opinion of the Court of Appeals for the Armed Forces is *United States v. Kisala* and is reported at 64 M.J. 50 (C.A.A.F. 2006). App. A, *infra,* at 1a. The principal opinion of the Navy-Marine Corps Court of Criminal Appeals is *United States v. Schwartz* and is published at 61 M.J. 567 (N-M. Ct. Crim. App. 2005). App. B, *infra* at 37a.

JURISDICTION

The Court of Appeals for the Armed Forces granted review of Petitioners' cases and affirmed their convictions on September 27, 2006. This Court's jurisdiction is invoked under 28 U.S.C. § 1259(3).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fifth Amendment to the Constitution reads, in part:

> No person … shall be compelled in any criminal case to be a witness against himself nor be deprived of life, liberty, or property, without due process of law….

The relevant provisions of 10 U.S.C. § 1107, are reproduced at App. C, *infra*, at 83a.

STATEMENT

This case raises important, recurring questions relating to the ability of the armed forces to compel servicemembers to receive unwanted medical treatment, including drugs used as a prophylaxis against biological and chemical warfare, and the validity of efforts by the Department of Defense (DoD) to circumvent Congress' intent that servicemembers not be compelled to submit to vaccination with investigational new drugs, or drugs unapproved for their applied use, without informed consent. Absent review by this Court, the decision of the Court of Appeals for the Armed Forces forecloses the ability of servicemembers to enforce the statutory prohibition against compelled injection into their bodies of investigational new drugs, or drugs unapproved for their applied use.

In 1999, Congress passed 10 U.S.C. § 1107, which invalidated a previous agreement between the Food and Drug Administration (FDA) and DoD wherein FDA had permitted DoD to compel servicemembers to receive experimental drugs when DoD determined that military necessity made it unfeasible to inform servicemembers that they were receiving experimental drugs. The new law, and later Executive Order 13139, prohibited DoD from compelling servicemembers to receive investigational new drugs, or drugs unapproved for their applied use, unless the servicemember gave informed consent, or unless the President waived the informed consent requirement due to military necessity.

In December 2003, the United States District Court for the District of Columbia issued a preliminary injunction barring DoD from compelling the plaintiffs to receive Anthrax Vaccine Absorbed (AVA) because the vaccine was both an investigational new drug, and a drug unapproved for its

applied use, and because 10 U.S.C. § 1107 prohibited the involuntary administration of such drugs to servicemembers. The District Court noted that it could not defer to FDA's determination regarding AVA's status because FDA had failed to provide a formal opinion as to AVA's investigational status. Eight days after the District Court issued the preliminary injunction, FDA issued a Final Order declaring AVA to be safe and effective and not misbranded.

The District Court reviewed FDA's final order in October 2004. The District Court issued a permanent, government-wide injunction, barring DoD from compelling servicemembers to receive AVA on the grounds that it was both an investigational new drug and a drug unapproved for its applied use, until FDA properly classified AVA as safe and effective for its intended use. The United States appealed the District Court's decision and, on February 9, 2006, the United States Court of Appeals for the District of Columbia Circuit held that the issue was moot because FDA had again classified AVA as safe and effective and not misbranded on December 19, 2005.

The Court of Appeals for the Armed Forces' holding that AVA has been licensed for use against weaponized inhalation anthrax since 1970, and that FDA's December 19, 2005, Final Order, was merely a "reaffirmation" of the drug's license is squarely at odds with the decisions in *Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003); *Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004) and the decision of the United States Court of Appeals for the District of Columbia Circuit in *Doe v. Rumsfeld*, 172 Fed. Appx. 327 (D.C. Cir. 2006).

An even more fundamental question, whether the military can ever compel servicemembers to receive unwanted medical treatment, should also be addressed by this Court. The United States Navy-Marine Corps Court of Criminal

Appeals held that this Court, in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), "found no constitutional right to refuse inoculation." *United States v. Schwartz*, 61 M.J. 567 (N-M. Ct. Crim. App. 2005). The lower court further held that servicemembers have no right to refuse unwanted medical treatment by virtue of their military status. Both of these issues merit further review.

A. Licensing of Anthrax Vaccine Absorbed

In 1972, FDA assumed responsibility for the licensure of biologics from the National Institutes of Health (NIH). The FDA immediately initiated the review of all biological products licensed by the NIH prior to July 1972. FDA Biologics Licensing Rule, 21 C.F.R. § 601.25 (1973). To accomplish this review, the Commissioner of FDA established advisory review panels to, among other things, "evaluate the safety and effectiveness of biologic products." *Id.* After the advisory panel had conducted its review, FDA was required to publish a proposed order with respect to the reviewed drug in the Federal Register and allow ninety days for public comment on the proposed order. *Id.* After the public had been afforded time to comment on the proposed licensing of the reviewed drug, FDA could then issue and publish a final order continuing or terminating the license for the drug.

In 1980, the Biologics Review Panel (BRP) recommended that FDA approve AVA for "individuals who may come in contact with imported animal hides, furs, bone meal, wool, hair (especially goat hair), and bristles; for all personnel and factories handling these materials and for individuals contemplating investigational studies involving *Bacillus Anthracis.*" *Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review,*

50 Fed. Reg. 51002 (Dec. 13, 1985). The BRP specifically noted, "[i]nhalation anthrax occurred too infrequently to assess the protective effect of the vaccine against this form of the disease." The BRP further noted that the "industrial setting in which the studies above were conducted is vanishing, precluding any further clinical studies" to establish AVA's efficacy against inhalation anthrax. Given the steadily shrinking population of workers requiring vaccination as protection against cutaneous anthrax, the BRP recommended that AVA be categorized as safe and effective "under the limited circumstances for which the vaccine is employed."

In 1985, FDA published a proposed rule to adopt the BRP's report verbatim with respect to AVA. "This product appears to offer significant protection against cutaneous anthrax in fully immunized subjects." The FDA did not issue a valid final order declaring AVA to be safe and effective for use as labeled until December 19, 2005 - years after Petitioners were ordered to receive the vaccine.

B. 10 U.S.C. 1107 and Executive Order 13139

Immediately prior to Operation *Desert Shield*, the Assistant Secretary of Defense for Health Affairs requested that FDA waive the requirement to obtain informed consent from military personnel should DoD deem it necessary to give servicemembers unapproved drugs or investigational new drugs (IND's). Informed Consent for Human Drugs and Biologics; Determination That Informed Consent is not Feasible, 55 Fed. Reg. 52814 (December 21, 1990). DoD argued that "military combat exigencies" made it unfeasible to inform its troops that it was giving them IND's or obtain their consent.

On December 21, 1990, FDA issued an interim regulation to amend its informed-consent regulations to

permit the Commissioner of FDA to make the determination that obtaining informed consent from military personnel with respect to IND's was not feasible. The regulation went into immediate effect due to the pending Operations *Desert Shield* and *Desert Storm*. The regulation required DoD to "collect data on the use of these products without informed consent." FDA was to review the data and revoke its previous waiver if necessary.

The FDA granted a waiver for DoD to use pyridostigmine bromide (PB) as pretreatment for nerve gas exposure. H.R. REP. NO. 105-388 at 374 (1997). Like AVA, FDA had already licensed PB for another purpose: treatment of the neuromuscular disorder myasthenia gravis, but not as a prophylaxis against nerve gas. PB pills were distributed to and ingested by U.S. military personnel under the threat of court-martial.

At the time it was ordering troops to take PB, DoD was aware, through its own research, that its use of PB "could produce long term health consequences, including nerve damage." *Id.* at 293. But it continued to issue it anyway. To make matters worse, DoD did not collect the data required by FDA's interim order and FDA did not question DoD's violation of the FDA-DoD agreement. *Id* at 373. The House Committee on Government Reform and Oversight described FDA's acquiesce as follows:

> The FDA meekly chastises the Defense Department for the failure to observe agreed-upon rules for the humane use of experimental drugs.

And, as with AVA, FDA did not publish a request for comments on its order as required by its regulations until July 29, 1997, seven years after it had authorized DoD to compel

its servicemembers to use experimental drugs. FDA "failed to devise better long-term methods governing military use of drugs and vaccines for CBW defense."

The failure of DoD and FDA to protect servicemembers from compelled participation in what amounted to uncontrolled human experiments led the House Committee on Government Reform and Oversight to recommend that the President alone have the authority to compel the use of IND's in all future cases. Eleven days later, 10 U.S.C. § 1107 was enacted giving the President alone the power to compel the use of IND's by servicemembers. On October 5, 1999, FDA revoked the 1990 interim final rule and issued a new regulation to govern DoD compliance with IND conditions and informed-consent waivers.

C. Mandatory Anthrax Vaccine Immunization Program

In 1995, DoD sent a letter to AVA's manufacturer, the Michigan Department of Public Health, proposing an investigational new drug study of the vaccine aimed at securing a license for the drug's use against inhalation anthrax. Attached to the letter was a study performed for the Department of Defense indicating that the vaccine was not licensed for inhalation anthrax. In a series of meetings over the course of 1996, DoD met with officials at the Michigan Department of Public Health and FDA to outline the scope of a study to support licensure of AVA for use against inhalation anthrax. These meetings culminated in the filing of an Investigational New Drug Application in September 1996, for the purpose of securing FDA approval for use against inhalation anthrax and a modified dosing schedule.

In March 1997, DoD changed its position on AVA's license regarding inhalation anthrax and solicited a letter from an FDA official suggesting that AVA's license included

inhalation anthrax. In the letter, Dr. Michael Friedman stated that DoD's intended use of AVA against weaponized inhalation anthrax was "not inconsistent" with AVA's license. The letter was not the official position of FDA. In 1997, FDA had still not issued a Final Order determining that AVA was safe and effective.

Despite the fact that FDA had not issued a Final Order declaring AVA to be safe and effective, DoD directed the mass vaccination of U.S. troops with AVA on May 18, 1998. Petitioners were ordered to receive AVA as part of DoD's mass vaccination program. They refused and were each court-martialed for disobeying orders from their superiors.

D. The District Court's Injunction

On December 22, 2003, the United States District Court for the District of Columbia found that the BRP's report and recommendations had never been acted upon or finalized by FDA. *Doe*, 297 F.Supp 2d at 124. Because FDA had not issued a final determination as to the safety and effectiveness of AVA, and because the pending IND application made AVA an IND with respect to inhalation anthrax, the District Court issued a preliminary injunction effectively terminating DoD's anthrax vaccination program because orders to take AVA were issued in violation of 10 U.S.C. § 1107. *Doe*, 297 F. Supp 2d at 135.

Eight days later, during the week between Christmas and New Years Eve 2003, and eighteen years after the BRP had made its recommendations, FDA rushed out a Final Rule and Final Order and declared AVA to be safe and effective regardless of the route of exposure. The FDA directed the District Court for the District of Columbia to consider its Final Order during further litigation in *Doe v. Rumsfeld*. The FDA also insisted that its December 30, 2003, Final Order had nothing to do with the District Court's December 23, 2003,

injunction and that the agency had made its determination "long before the court's ruling."

On October 27, 2004, the District Court for the District of Columbia set aside FDA's Final Order of December 30, 2003. The District Court held that FDA had not complied with the Administrative Procedures Act when it issued its Final Order. Specifically, the District Court found that FDA should have reopened the period for public comment on its Final Order because its order constituted a significant departure from the position FDA had previously taken in its Proposed Rule in 1985, and because the Final Order relied on large amounts of new evidence not relied upon in its Proposed Rule. The District Court further found the DoD's anthrax vaccination program to be illegal and in violation of federal law because DoD was injecting military members with an IND and a drug unapproved for its applied use. The court permanently enjoined DoD from ordering servicemembers to submit to vaccination with AVA until FDA properly determined that the drug was safe and effective.

E. The Lower Court's Decision

Contrary to the decision of the United States District Court for the District of Columbia, the Court of Appeals for the Armed Forces held that AVA has always been licensed for use against weaponized inhalation anthrax since 1970. *United States v. Kisala*, 64 M.J. 50 (C.A.A.F. 2006); *United States v. Rose*, 64 M.J. 56 (C.A.A.F. 2006). And, although the United States, in the proceedings before the District Court in *Doe*, did not dispute that AVA was an IND until the vaccine's manufacturer withdrew its Investigational New Drug Application in February 2004, the Court of Appeals for the Armed Forces concluded AVA was never an IND. The

court gave "considerable deference" to the same FDA orders that the District Court had previously invalidated and had held were not entitled to deference because FDA had violated the Administrative Procedures Act. *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 9 (D.D.C. 2004). And the Court found that the final order issued by FDA on December 19, 2005, which the District Court had held was required to approve AVA for DoD's intended use, was merely a "clarification" and a "reaffirmation" of AVA's long-approved use as a prophylaxis against biological warfare. In fact, as noted by the Court of Appeals for the District of Columbia Circuit, FDA did not classify AVA as safe and effective for its applied use, thus dissolving the permanent injunction issued by the District Court, *until* it issued its Final Rule and Order on December 19, 2005. *Doe v. Rumsfeld*, 172 Fed. Appx. 327 (D.C. Cir. 2006).

REASONS FOR GRANTING THE PETITION

The decision below creates a conflict between military and civilian courts - courts of unequal jurisdiction - as to whether AVA was a drug unapproved for its applied use and an investigational new drug at the time Petitioners were ordered to receive the drug, and whether Petitioners could have been compelled to receive AVA in light of 10 U.S.C. § 1107. The lower court's willingness to give deference to the FDA order that the District Court held was entitled to no deference, and that it ultimately invalidated more than a year before the lower court's decision, has put the military courts squarely at odds with their civilian counterparts. This conflict has led to the absurd result that the orders given to Petitioners, and those similarly situated, were simultaneously illegal, according to the government-wide injunction issued by the District Court, and legal, according to the Court of

Appeals for the Armed Forces. Only this Court can resolve this conflict. Absent review by this Court, the military convictions of those servicemembers who refused orders to receive AVA will be final.

Additionally, the lower court's determination that servicemembers do not have the right to refuse unwanted medical treatment, by virtue of their status as members of the armed forces, is an important issue decided by the lower court that has not, but should be, addressed by this Court.

I.

Military and Civilian Courts are Divided Over Whether Federal Law Permitted DoD to Order Servicemembers to Receive AVA Before FDA Issued its December 19, 2005 Final Order.

In *Doe v. Rumsfeld*, 297 F. Supp. 119, 135 (D.C.C. 2003), the District Court found AVA to be an investigational new drug and a drug "being used for an unapproved purpose." *Id.* The Court found that the DoD, in ordering troops to receive the vaccine, was in violation of 10 U.S.C. § 1107, Executive Order 13139, and DoD Directive 6200.2. "Absent an informed consent or presidential waiver, the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Id.*

On December 30, 2003, eight days after the District Court's decision, FDA issued a Final Order classifying AVA as safe and effective to protect against all routes of exposure to anthrax. After review, the District Court invalidated the FDA's December 30, 2003, Final Order because FDA had not followed its own rules in promulgating its Final Order in accordance with the Administrative Procedures Act. The Court issued a permanent injunction until "FDA properly classifies AVA as a safe and effective drug for its intended

use...." *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 19 (D.D.C. 2004). "Accordingly, the involuntary anthrax vaccination program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver." *Id.*

The Court of Appeals for the Armed Forces held that Petitioners had failed to establish that "the vaccine is an investigational new drug or a drug unapproved for its applied use" and that the orders to receive AVA did not therefore violate 10 U.S.C. § 1107. *United States v. Kisala*, 64 M.J. 50 (C.A.A.F. 2006). The Court found that AVA had been continuously licensed for DoD's intended purpose since 1970. *Id.* Inexplicably, the Court gave "a high degree of deference" to the FDA order that had already been invalidated by the District Court in *Doe*.

The conflict between military and civilian courts is compounded by the fact that the dispute is between courts that are not of equal jurisdiction. The Court of Appeals for the Armed Forces, and the Service Courts of Criminal Appeals, are courts of limited jurisdiction and have no authority to decide issues concerning the licensure of drugs or the FDA's compliance with the Administrative Procedures Act in approving a drug. *Clinton v. Goldsmith*, 526 U.S. 529 (1999). By contrast, such matters are squarely within the jurisdiction of the Federal District Courts and the Federal Circuit Courts of Appeals, and these courts are routinely called upon to decide such issues. It is therefore unclear what jurisdictional authority, if any, the Court of Appeals for the Armed Forces possessed that would enable it to disagree with the District Court's conclusion that, until December 19, 2005, FDA was not licensed for use against inhalation anthrax and that DoD's AVIP was in violation of Federal Law.

The conflict is further aggravated by the fact that thousands of servicemembers who refused orders to refuse AVA, and were administratively punished by DoD, may now

obtain relief in civilian courts for DoD's failure to comply with 10 U.S.C. § 1107, but, as a result of the Court of Appeals for the Armed Forces' decision, those who were court-martialed will forever have a federal military conviction and the lasting ignominy of a punitive discharge. Only this Court can resolve this conflict.

II.

The Lower Court has Decided the Important Question of Whether the 1.2 Million Servicemembers who are now Required to Receive AVA Under Threat of Court-Martial May be Compelled to do so, in a way that Conflicts with Relevant Decisions of this Court.

On October 16, 2006, DoD announced that it would again resume its mandatory AVIP. According to DoD, since its program was made voluntary as a result of the District Court's injunction, only fifty-percent of servicemembers deploying to high threat areas had elected to receive AVA. Under the new program, all servicemembers deployed to high threat areas will be required to receive AVA.

The lower court, citing *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), held that there is no constitutional right to refuse inoculation. *Schwartz*, 61 M.J. at 573. "We are confident that the Supreme Court never intended *Cruzan* or *Sell* to impede vaccination programs in either civilian or military contexts." *Id.* The Court further held that, even if there were a constitutional right to refuse vaccination, it did not apply to servicemembers "whose personal liberty interests are often limited to preserve good order and discipline and fulfill military missions." *Id.*

The lower court's decision conflicts with relevant decisions of this Court. In *Jacobson*, this Court upheld a

Massachusetts statue requiring vaccination against smallpox because the law had a real and substantial relation to the protection of the public health and safety. *Jacobson*, 197 U.S. at 31. The lower court's decision went further, saying that there is no right to refuse inoculation under any circumstances, a holding that is in direct conflict with *Jacobson* and the more recent decisions of this Court in *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 278 (1990), *Washington v. Halper*, 494 U.S. 210, 221-222 (1990), *Sell v. United States*, 539 U.S. 166, 181 (2003).

Individuals have a constitutionally-protected liberty interest in refusing unwanted medical treatment. *Cruzan*, 497 U.S. at 278. This Court has also held, "[t]he forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty." *Halper*, 494 U.S. at 221-222.

But determining that a person has a "liberty interest" under the Due Process Clause does not end the inquiry. "[W]hether respondent's constitutional rights have been violated must be determined by balancing his liberty interests against relevant state interests." *Youngberg v. Romero*, 457 U.S. 307, 321 (1982).

In *Sell*, this Court applied four factors in balancing the state's important interests against the right of accused to refuse the involuntarily administration of medication solely for trial competence purposes: (1) a court finds that important governmental interests are at stake, (2) the involuntary medication will significantly further those concomitant state interests, (3) that the involuntary medication is necessary to further those interests, (4) and that the administration of the drugs is medically appropriate. *Sell*, 539 U.S. at 181. The purpose of these standards is to determine if the involuntary administration of drugs is necessary to further a particular governmental interest. *Sell*, 539 U.S. at 181.

Contrary to the holding of the lower court, the jurisprudence of this Court indicates that there is a right to refuse unwanted medical treatment, including vaccinations, but that this right must be balanced against the state interests involved. In this case, when the important government interests in this case are balanced against the right to refuse unwanted medical treatment, the impermissible infringement upon Petitioners' liberty interest becomes clear.

Petitioners do not dispute that there are important government interests at issue in this case. The lower court has held, "[t]he military, and society at large, have a compelling interest in having those who defend the nation remain healthy and capable of performing their duty." *United States v. Womack*, 29 M.J. 88, 90 (C.M.A. 1989). Indeed the military exists to successfully prosecute this nation's wars and defend the nation's interests.

But the United States has failed to demonstrate how involuntary vaccination will significantly further the legitimate state interest of protecting military members against weaponized inhalation anthrax. In 1980, the BRP recommended that FDA approve AVA for "individuals who may come in contact with imported animal hides, furs, bone meal, wool, hair (especially goat hair), and bristles; for all personnel and factories handling these materials and for individuals contemplating investigational studies involving *Bacillus anthracis*." The BRP specifically noted,"[i]nhalation anthrax occurred too infrequently to assess the protective effect of vaccine against this form of the disease." The BRP further held, "this vaccine appeared 93 percent protective against cutaneous anthrax. No meaningful assessment of its value against inhalation anthrax is possible due to its low incidence." Accordingly, there is no indication that DoD's AVIP significantly furthers the legitimate state interest of protecting military members against weaponized

inhalation anthrax.

Further, the United States has failed to demonstrate that involuntary vaccination is necessary to further the legitimate state interest of protecting its troops against weaponized inhalation anthrax. In assessing this factor, this Court must find that any alternative, less intrusive means are unlikely to achieve substantially the same results. *Sell*, 539 U.S. at 181.

According to the Centers for Disease Control and Prevention, anthrax will not penetrate the materials of properly assembled and fitted respirators or protective clothing. Further, inhalation anthrax can be successfully treated with antibiotics. Because the United States has at its disposal less intrusive means with which to combat weaponized inhalation anthrax, the draconian measure of forcible injection of medication is an impermissible infringement on the liberty interests of Petitioners.

This Court has upheld an infringement upon this liberty interest only where forcible vaccination was the only means to prevent virulent diseases from sweeping through the entire community. *Jacobson*, 197 U.S. at 29. That case dealt with smallpox, a highly contagious virus for which there is no cure and no means of treatment. But unlike smallpox, Anthrax is a bacterium and is not spread from one person to another. And Anthrax can be successfully treated with antibiotics and infection can be prevented altogether with use of protective equipment. Accordingly, forcible vaccination to prevent anthrax infection is not necessary to protect the health and welfare of the military community. Petitioners' refusal to receive AVA posed no substantial threat to public health and safety in the military. The unjustified infringement upon Petitioners' liberty interest in this case is not constitutionally permissible and the orders directing them to receive AVA were illegal.

Even more disturbing than the lower court's holding that

there is no constitutional right to refuse unwanted vaccination, is the lower court's determination that, even if such a right existed, it does not apply to servicemembers. *Schwartz*, 61 M.J. at 573. It is disturbing because of the DoD's long history of medical experimentation on servicemembers dating back to World War II when approximately 60,000 servicemembers were intentionally exposed to chemical warfare agents. In this case, the District Court issued an injunction to stop DoD from involuntary vaccination because servicemembers were again being used "as guinea pigs for experimental drugs."

This Court has long held that the nature of military service "may render permissible within the military that which would be constitutionally impermissible outside it." *Parker v. Levy*, 417 U.S. 733, 758 (1974). But this Court has never held that the identified fundamental rights of procreation,[1] marriage,[2] some private sexual activity,[3] and the right to refuse medical treatment are diminished simply because a citizen has donned a military uniform. "It is a promise of the Constitution that there is a realm of personal liberty which the government may not enter." *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 847 (1992).

It has long been held that "our citizens in uniform may not be stripped of basic rights simply because they have doffed their civilian clothes." Earl Warren, *The Bill of Rights and the Military*, 37 N.Y.U.L. Rev. 181, 188 (1962). The lower court's decision that there is no right to refuse unwanted vaccination, and that even if such a right existed, it does not apply to servicemembers by virtue of their military

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[1] *Griswold v. Connecticut*, 381 U.S. 479 (1965).
[2] *Loving v. Virginia*, 388 U.S. 1 (1967).
[3] *Lawrence v. Texas*, 539 U.S. 558 (2003).

status, is in conflict with relevant decisions of this Court.

III.

The Lower Court's Decision is Incorrect.

The United States District Court for the District of Columbia correctly determined that AVA was both an IND and a drug unapproved for its applied use. *Doe*, 297 F. Supp. at 135. The Court of Appeals for the Armed Forces sought to explain away the conflict between its decision and the decision of the District Court by saying that the District Court's "evaluation of the civil remedies differs from our evaluation of the criminal charges that arise in the military context of Appellant's willful disobedience of a presumed lawful order." *Kisala*, 64 M.J. at 53. The lower court held that the "linchpin" of Petitioners' cases was the presumed legality of military orders - a matter the District Court's opinions "neither recognize nor address...." *Id.*

The lower court's opinion inexplicably ignores, the District Court's extended discussion of the ability of servicemembers to challenge presumptively lawful orders. *Doe*, 297 F. Supp. 2d at 129-30. (citing *New v. Cohen*, 129 F.3d 639 (D.C. Cir. 1997)), the District Court noted that the plaintiffs in *Doe* had two options: they could have obeyed the orders and then sought judicial review of the orders as the plaintiffs in *Doe* had done, or they could have disobeyed the orders and challenged their validity at their subsequent courts-martial. *Id.* The District Court's decision was not merely an "evaluation of civil remedies", but *direct judicial review* of the lawfulness of the orders given to the servicemembers in *Doe*. And, as a result of the District Court's decisions, and those of the Court of Appeals for the Armed Forces, the orders given to those who sought injunctive relief have been determined to have been illegal,

while the same orders given to Petitioners, who simply disobeyed the orders and challenged their lawfulness at their courts-martial, have been determined to be valid.

The lower court's determination that District Court's decision did not address presumptive legality of the orders issued to the plaintiffs in *Doe* is as erroneous as its determination that AVA was neither an IND nor a drug unapproved for its applied use at the time Petitioners were ordered to receive the drug.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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Appendix A

UNITED STATES, Appellee v. Andrew J. KISALA, Specialist U.S. Army, Appellant

No. 04-0246

UNITED STATES COURT OF APPEALS FOR THE ARMED FORCES

64 M.J. 50; 2006 CAAF LEXIS 1222

December 8, 2005, Argued
September 27, 2006, Decided

Counsel for Appellant: Captain Todd N. George (argued); Colonel Mark Cremin, Colonel Robert D. Teetsel, Lieutenant Colonel Mark Tellitocci, Major Sean S. Park, and Captain Jeremy W. Robinson (on brief).

Counsel for Appellee: Captain Michael C. Friess (argued); Colonel Lauren B. Lecker, Colonel Steven T. Salata, Lieutenant Colonel Margaret B. Baines, Lieutenant Colonel Theresa A. Gallagher, Lieutenant Colonel Mark L. Johnson, Major Natalie A. Kolb, Captain Mark J. Hamel, and Captain Edward E. Wiggers (on brief).

Amicus Curiae: Lieutenant Brian L. Mizer, JAGC, USN, and Captain Pamela A. Holden, JAGC, USN, for the

United States Navy-Marine Corps Appellate Defense Division (on brief).

GIERKE, C.J., delivered the opinion of the Court, in which CRAWFORD, EFFRON, BAKER, and ERDMANN, JJ., joined.

OPINION BY: GIERKE

OPINION: Chief Judge GIERKE delivered the opinion of the Court.

Appellant was convicted, contrary to his pleas, of willfully disobeying a lawful order of his superior commissioned officer to receive an anthrax vaccination.[1] Appellant has challenged the lawfulness of the order. We hold that Appellant has not rebutted the presumption that the order was lawful. In particular, Appellant has not demonstrated that the order relied improperly upon interpretations by the Food and Drug Administration (FDA) of the long-standing approved license to administer this specific Vaccine.[2]

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[1] Appellant's offense was a violation of Article 90, Uniform Code of Military Justice (UCMJ), 10 U.S.C. § 890 (2000).

[2] Anthrax Vaccine Adsorbed is the vaccine that was the subject of this order. Although it is commonly referred to as "AVA," this opinion refers to it as the "Vaccine."

I. FACTS

Appellant's Battalion Commander issued a direct order to Appellant on August 24, 2000, in the presence of the sergeant major, the company commander, and the first sergeant, to receive the anthrax vaccination by the close of business that day. Due to the limited availability of the Vaccine at Fort Bragg at the time, there was difficulty locating a clinic where Appellant would be able to receive the inoculation. A clinic with the Vaccine was not located until after 1600 hours on August 24, 2000. Because it would have been difficult to transport Appellant to the clinic in time to receive the shot prior to the termination of routine clinic hours, the battalion commander and the company commander extended the time for Appellant to comply with the order to August 25, 2000.

On the morning of August 25, 2000, the company commander issued Appellant a written counseling statement reiterating the battalion commander's order to receive the anthrax vaccination prior to 1700 hours on August 25, 2000. Appellant signed this statement thereby acknowledging his understanding of the order. At the time of the counseling statement, Appellant was told that the Vaccine was available and that the company commander was willing and able to take Appellant to the clinic to receive the Vaccine.

Appellant refused to receive the Vaccine and was charged with willfully disobeying the lawful order of a superior commissioned officer in violation of Article 90, UCMJ. Contrary to his pleas, Appellant was convicted of this offense (with the date August 25, 2000, substituted for August 24, 2000). The military judge sentenced Appellant to be reduced to pay grade E-1, confined for thirty days and to be discharged from the service with a bad-conduct discharge. The convening authority approved the sentence as adjudged. The United States Army Court of Criminal Appeals affirmed the findings and sentence as approved.[3]

This Court granted review of the following issue:
WHETHER THE ORDER THAT APPELLANT SUBMIT TO AN ANTHRAX VACCINATION ON AUGUST 24, 2000, WAS A LAWFUL ORDER UNDER THE CIRCUMSTANCES AT THAT TIME.[4]

II. DISCUSSION

Long ago this Court recognized the foundational principle of military discipline: "Fundamental to an effective armed force is the obligation of obedience to lawful orders."[5] Reflecting the authority of this principle,

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[3] United States v. Kisala, No. Army 20000930 (A.F. Ct. Crim. Dec. 22, 2003).

[4] United States v. Kisala, 60 M.J. 128 (C.A.A.F. 2004).

[5] Lee v. Pearson, 18 C.M.A. 545, 546, 40 C.M.R. 257, 258 (1969) (quoting United States v. Noyd, 18 C.M.A.

an order is presumed to be lawful, and a subordinate disobeys an order at his own peril.[6] However, a servicemember may challenge the lawfulness of an order

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483, 491, 40 C.M.R. 195, 203 (1969)). Indeed, a professional military institution could not otherwise function without a service member having a duty to obey lawful orders.

[6] Manual for Courts-Martial, United States pt. IV, para. 14.c.(2)(a)(i) (2005 ed.) (MCM), states:

An order requiring the performance of a military duty or act may be inferred to be lawful and it is disobeyed at the peril of the subordinate. This inference does not apply to a patently illegal order, such as one that directs the commission of a crime.

See also United States v. New, 55 M.J. 95, 108 (C.A.A.F. 2001); United States v. Hughey, 46 M.J. 152, 154 (C.A.A.F. 1997); United States v. Nieves, 44 M.J. 96, 98 (C.A.A.F. 1996); United States v. Womack, 29 M.J. 88, 90 (C.M.A. 1989); Unger v. Ziemniak, 27 M.J. 349, 359 (C.M.A. 1989); Nico Keijzer, Military Obedience 97-98, 155-71 (1978); William Winthrop, Military Law and Precedents 575-76 (2d ed. 1920 reprint); see generally William C. De Hart, Observations on Military Law and the Constitution and Practice of Courts-Martial 165-66 (1946).

at the time it is given or in later disciplinary proceedings.[7]

This Court has outlined the essential attributes of a lawful order that sustain the presumption of lawfulness to include: "(1) issuance by competent authority – a person authorized by applicable law to give such an order; (2) communication of words that express a specific mandate to do or not do a specific act; and (3) relationship of the mandate to a military duty."[8] In light of the presumption of lawfulness, long-standing principles of military justice place the burden of rebutting this presumption on the accused.[9]

In this case, Appellant is attempting to overcome this

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[7] This opinion, while relying on the presumption of lawfulness, is not inconsistent with R.C.M. 916(d) under which, "It is a defense to any offense that the accused was acting pursuant to orders unless the accused knew the orders to be unlawful or a person of ordinary sense and understanding would have known the orders to be unlawful."

[8] United States v. Deisher, 61 M.J. 313, 317 (C.A.A.F. 2005); MCM pt. IV, para. 14.c.(2)(a)(ii)-(iii), para. 14.c.(2)(d); see also Noyd, 18 C.M.A. at 489, 40 C.M.R. at 201 (presenting examples of when an order may be unlawful).

[9] United States v. Hughey, 46 M.J. 152, 154 (C.A.A.F. 1997).

presumption of the lawfulness of the order to receive the Vaccine. Appellant's assertion that the order was unlawful has two components. First, Appellant claims that the Vaccine is an investigational new drug or a drug unapproved for its applied use as a vaccine against inhalation anthrax. Second, Appellant claims that the order to receive this investigational new drug violated federal law and was therefore unlawful.[10]

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[10] Appellant asserts that 10 U.S.C. § 1107 (2000), and Exec. Order 13, 139, 64 Fed. Reg. 54,175 (Oct. 5, 1999), confer upon him a right to refuse the order to receive the Vaccine. The relevant portions of these two authorities appear below.

10 U.S.C. § 1107:

(a)(1) Whenever the Secretary of Defense requests or requires a member of the armed forces to receive an investigational new drug or a drug unapproved for its applied use, the Secretary shall provide the member with notice containing the information specified in subsection (d)

. . . .

(d) Content of notice. The notice required under subsection (a)(1) shall include the following: (1) clear notice that the drug being administered is an investigational new drug or a drug unapproved for its applied use. (2) The reasons why the investigational new drug or drug unapproved for its applied use is being administered. (3) Information regarding the possible side

We conclude that Appellant's argument fails with regard to both components and address them in turn.

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effects . . . . (4) Such other information that, as a condition of authorizing the use of the investigational new drug or drug unapproved for its applied use, the Secretary of Health and Human Services may require to be disclosed.

Exec. Order 13,139:
Sec. 3. Informed Consent Requirement and Waiver Provision. (a) Before administering an investigational drug to members of the Armed Forces, the Department of Defense (DOD) must obtain informed consent from each individual . . . .

Sec. 6. (a) This order applies to the consideration and Presidential approval of a waiver of informed consent under 10 U.S.C. § 1107 and does not apply to other FDA regulations.

(b) This order is intended only to improve the internal management of the Federal Government. Nothing contained in this order shall create any right or benefit, substantive or procedural, enforceable by any party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

APPELLANT'S ASSERTION THAT THE VACCINE WAS AN INVESTIGATIONAL NEW DRUG OR DRUG UNAPPROVED FOR ITS APPLIED USE

To support his argument, Appellant made several allegations regarding the status of the Vaccine. Appellant first asserts that the Food and Drug Administration initiated an investigation into the Vaccine but never issued a final rule approving use of the Vaccine to protect against inhalation anthrax. Second, Appellant asserts that the Vaccine's manufacturer, working in conjunction with the Department of Defense (DoD), filed an investigational new drug application in 1996.[11] According to Appellant, this application proposed to conduct investigations that would support specifically adding "inhalation anthrax" to the Vaccine label.

Appellant also asserts that the Vaccine was and is an investigational new drug unapproved for its applied use -

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[11] The Michigan Department of Public Health (MDPH) filed an Investigational New Drug Application in 1996. "The manufacturer's stated purpose for filing the application was 'to conduct clinical investigations designed to investigate changes in the approved labeling for the licensed product. The potential labeling would affect the specific clinical indication, route and vaccination schedule for AVA.'" Doe v. Rumsfeld, 297 F. Supp. 2d 119, 132 (D.D.C. 2003) (quoting letter from MDPH to Dr. Kathryn C. Zoon (Oct. 20, 1996)).

- to protect against inhalation anthrax. In support of this argument, Appellant relies on two successive and related federal district court opinions that issued first a temporary and then a permanent injunction preventing the DoD from subjecting military personnel to involuntary anthrax vaccinations absent informed consent or a presidential waiver.[12]

The federal district court's evaluation of the civil remedies differs from our evaluation of the criminal charges that arise in the military context of Appellant's willful disobedience of a presumed lawful order. The linchpin of this case is the presumed legality of the military order to receive the Vaccine. The district court opinions neither recognize nor address this critical presumption.

Additionally, on appeal from this decision, the United States Court of Appeals for the District of Columbia Circuit noted that the parties "still dispute whether [the Vaccine]'s original 1970 license takes it outside the definition of a 'drug unapproved for its applied use' within the meaning of 10 U.S.C. § 1107(g)(2)."[13] In noting this disagreement of the parties, the court expressly declined to resolve that issue because it would have no impact on the litigants in the case. Moreover, the D.C. Circuit highlighted that the injunction issued by

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[12] Doe, 297 F. Supp. 2d at 135; Doe v. Rumsfeld, 341 F. Supp. 2d 1, 15-16 (D.D.C. 2004).

[13] Doe v. Rumsfeld, 172 Fed. Appx 327, 328, 2006 U.S. App. LEXIS 3275, at *3 (D.C. Cir. 2006).

the district court in 2004, by its own terms, remained in effect until the FDA classified the Vaccine as safe and effective for its intended use. The D.C. Circuit also noted that after the district court issued the permanent injunction, the FDA issued a clarification on December 19, 2005.[14] Therefore, once this classification was issued, the injunction was dissolved.

As stated above, there is a presumption that orders are lawful.[15] Under this presumption, the servicemember challenging the order bears the burden of demonstrating the illegality. Where, as here, we are faced with an order based upon a rule promulgated by an agency outside the normal purview of our Court, we should treat the agency's administrative determinations with considerable deference.[16] Given this degree of deference to the determinations of the FDA, the burden on the servicemember challenging the rule is particularly high.

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[14] Doe, 172 Fed. Appx at 328; 2006 U.S. App. LEXIS 3275, at *2

[15] See supra note 6.

[16] Cf. Auer v. Robbins, 519 U.S. 452, 461, 117 S. Ct. 905, 137 L. Ed. 2d 79 (1997) (an agency's interpretation of its own regulation is entitled to deference); Udall v. Tallman, 380 U.S. 1, 16, 85 S. Ct. 792, 13 L. Ed. 2d 616 (1964) ("[T]his Court shows great deference to the interpretation given the statute by the [] agency . . . . When the construction of an administrative regulation rather than a statute is in issue, deference is even more clearly in order.").

The National Institute of Health (NIH) licensed the Vaccine for use against anthrax in 1970.[17] In 1972, the authority to license biological drugs shifted to the FDA.[18] The licenses for drugs approved by the NIH remained effective unless and until the FDA actively decided to suspend or revoke the license.[19] The Vaccine's license has never been suspended or revoked. Additionally, Appellant has not shown that the license was erroneously granted. He has, therefore, not overcome the presumption that the order to receive the Vaccine was lawful.

In 1973 the FDA established a two-stage process for reviewing biological products licensed prior to July 1, 1972.[20] This two-stage process was composed of an advisory review panel, and a request for "data and

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[17] 36 Fed. Reg. 8704-05 (May 11, 1971), see also Hearing to Review the Dep't of Defense Anthrax Vaccine Immunization Program Before the S, Comm. on Armed Services, 106th Cong. 9 (2000) (written statement of FDA), available at http://armed-services.senate.gov/statemnt/2000/000413fd.pdf.

[18] See Press Release, FDA Issues Final Rule and Final Order Regarding Safety and Efficacy of Certain Licensed Biological Products Including Anthrax Vaccine, (Dec. 30, 2003).

[19] 21 C.F.R. § 601.4 (2004); 21 C.F.R. § 601.4 (1977).

[20] 21 C.F.R. § 601.25 (1974).

views."[21]

In accordance with this review, the FDA directed an independent panel of nongovernmental scientists and medical personnel to review the safety and labeling of biological products that had been licensed prior to July 1, 1972.[22] According to 21 C.F.R. 601.25, the panel was: "(1) to evaluate the safety and effectiveness of biological products for which a license has been issued . . . (2) to review the labeling of such biological products, and (3) to advise [the FDA Commissioner] on which of the biological products under review are safe, effective, and not misbranded."[23]

The Vaccine was included in this review of all biological products licensed prior to July 1972. The expert panel recommended that the Vaccine, originally licensed in 1970, be classified as a Category I product.[24] This classification indicates that the Vaccine was safe and effective as labeled. The panel recommended that the Vaccine continue to be licensed on the basis of the evidence of its safety and effectiveness.[25]

As required by 21 C.F.R. § 601.25, the proposed rule required public comment, and the FDA received four

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[21] Id. § 601.25(a), (b).

[22] Id. § 601.25(a).

[23] Id.

[24] 50 Fed. Reg. 51,002-03, 51,058-59, (Dec. 13, 1985).

[25] Id. at 51,059.

total comments, none of which addressed the Vaccine.[26]

In 1996, the Vaccine's manufacturer submitted an investigational new drug application to the FDA.[27] The application identified three areas in which the current anthrax license could be modified: (1) the labeling of the Vaccine, (2) the administration method, and (3) the dosage.[28] It is important to note that this application is limited to the three listed purposes and had no effect on the original license of the Vaccine or its subsequent recognition as safe and effective.

The licensing history reflects that the Vaccine has been licensed as approved for anthrax inoculation since 1970[29] without interruption, revocation, or suspension. Moreover, the agency approval has been reaffirmed as recently as December 19, 2005.[30]

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[26] See 70 Fed. Reg. 75,180, 75,182 (Dec. 19, 2005).

[27] See supra note 11.

[28] See Doe, 297 F. Supp. 2d at 132 (citing letter from MDPH to Dr. Kathryn C. Zoon (Oct. 20, 1996)). The introductory statements to the 1996 Investigational New Drug (IND) application likewise provided that "the ultimate purpose of the IND is to obtain a specific indication for inhalation anthrax and a reduced vaccination schedule." Doe, 297 F. Supp. 2d at 132 (quoting introductory statement to the IND application (Sept. 20, 1996)).

[29] 36 Fed. Reg. 8704.

[30] 70 Fed. Reg. 75,180, 75,182.